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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/17/2001

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EXAMINER

SANDALS, WILLIAM O

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 12/17/2001

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/619,144

Applicant(s)
Mohr et al.

Examiner
William Sandals

Art Unit
1636



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 1, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above, claim(s) 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 19-27 is/are rejected.
- 7) ☒ Claim(s) 16-18 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jul 19, 2000 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 20) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of claims 1-27, Group I in Paper No. 7, filed November 1, 2001 is acknowledged. The traversal is on the ground(s) that there is no serious burden on to search both of Groups I and II, and that no "appropriate explanation" was given of the restriction of the Groups I and II. This is not found persuasive because as explained in the restriction requirement in the previous office action, the apparatus of Group I is patentably distinct from the claimed method of Group II due to the fact that the method may be practiced in another apparatus. This is the explanation for the restriction. The two groups are classified separately, demonstrating the necessity for separate searches. Thus the explanation has been provided, as well as the grounds for separate searches. This being the case, the groups are patentably distinct and the restriction requirement is sustained.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on January 19, 1998. It is noted, however, that applicant has not filed a certified copy of the German application as required by 35 U.S.C. 119(b).

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Drawings

3. New formal drawings are required in this application because the 8th edition of MPEP, 608.02(b) no longer permits drawings to be held in abeyance. A copy of PTO form 948, Notice of Draftsperson's Patent Drawing Review is enclosed. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the Patent and Trademark Office no longer prepares new drawings.

Specification

4. The use of the trademark MS-DOS has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

5. Claim 2 is objected to because of the following informalities: at line 2, the word "each" appears in a context that would imply multiple culture inserts, where the claim asserts "at least one" and does not provide language which provides for multiple inserts. Appropriate correction is required.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. Claim 3 recites the limitation "the individual culture containers" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.
9. Claim 6 recites at lines 2-3 "the corresponding cell culture insert lies in a common horizontal plane". No other mention has been found in claims 6 or 1 which asserts a "horizontal plane", making the reference to a "common horizontal plane" unclear.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-15 and 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,710,043 in view of GB 2,314,343 (of record) and US 5,707,869.

The claims are drawn to a culturing device with a culture container for receiving or discharging a culture medium, a removable cell culture insert and a supply mechanism with a

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liquid level sensor, such that the supply mechanism provides culture medium to the container at a low level and at a high level. Gas may be supplied to the container. There may be multiple culture containers. There may be a programmable controller to control the supply of the medium to the container at the required levels.

US 5,710,043 taught (see especially the abstract, summary, figures and column 3) a culturing device with a culture container for receiving or discharging a culture medium, at least one removable cell culture insert and a means for varying the level of the tissue culture medium. Gas may be supplied to the container. There may be multiple culture containers.

US 5,710,043 did not teach a supply mechanism with a liquid level sensor, such that the supply mechanism provides culture medium to the container at a low level and at a high level, nor that there may be a programmable controller to control the supply of the medium to the container at the required levels.

GB 2,314,343 taught (see especially the abstract, pages 5-6 and the claims) a culturing device with a culture container for receiving or discharging a culture medium and a supply mechanism with a liquid level sensor, such that the supply mechanism provides culture medium to the container at a low level and at a high level. Gas may be supplied to the container. There may be a programmable controller to control the supply of the medium to the container at the required levels.

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US 5,707,869 taught (see especially column 2, the summary and the figures) a tissue culture device with multiple containers with variable levels of medium and a mechanism for the supply of a gas and multiple containers.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of US 5,710,043 with GB 2,314,343 and US 5,707,869 to produce the instant invention because each of US 5,710,043, GB 2,314,343 and US 5,707,869 taught a cell culture device which provided for variable levels of the culture medium and a supply of gas to the container. GB 2,314,343 taught the desirable effect of having a controller for varying the level of the culture medium and US 5,707,869 taught the desirable use of multiple containers for simultaneous tissue culture chambers in a single apparatus.

One of ordinary skill in the art would have been motivated to combine the teachings of US 5,710,043 with GB 2,314,343 and US 5,707,869 to produce the instant invention because GB 2,314,343 taught the desirable use of a sensor and a controller for alternating between minimal levels of tissue culture medium and maximal levels of tissue culture medium to provide adequate exposure of the cells to the gas in the culture container. US 5,710,043 taught that there may be more than one cell culture insert, where US 5,707,869 taught the desirable use of multiple containers in a single device.

Allowable Subject Matter

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12. Claims 16-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

13. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Friday from 8:30 AM to 5:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott can be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.
Examiner
December 15, 2001


TERRY MCKELVEY
PRIMARY EXAMINER

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.